presents

Healthcare Fraud and Abuse in a Tougher Enforcement Environment

Lessons Learned From Recent DOJ/HHS Fraud Investigations, Prosecutions and Settlements

A Live 90-Minute Teleconference/Webinar with Interactive Q&A

Today's panel features:
Michael W. Paddock, Partner, **Crowell & Moring**, Washington, D.C.
Robert C. Threlkeld, Partner, **Morris Manning & Martin**, Atlanta
Michael A. Dowell, Partner, **Hinshaw & Culbertson**, Los Angeles

Thursday, April 8, 2010

The conference begins at:
1 pm Eastern
12 pm Central
11 am Mountain
10 am Pacific

You can access the audio portion of the conference on the telephone or by using your computer's speakers.
Please refer to the dial in/ log in instructions emailed to registrations.

CLICK ON EACH FILE IN THE LEFT HAND COLUMN TO SEE INDIVIDUAL PRESENTATIONS.

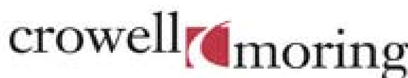
If no column is present: click **Bookmarks** or **Pages** on the left side of the window.

If no icons are present: Click **View**, select **Navigational Panels**, and chose either **Bookmarks** or **Pages**.

If you need assistance or to register for the audio portion, please call Strafford customer service at **800-926-7926 ext. 10**

For CLE purposes, please let us know how many people are listening at your location by

- closing the notification box
- and typing in the chat box your company name and the number of attendees.
- Then click the blue icon beside the box to send.



Healthcare Fraud & Abuse In A Tougher Enforcement Environment:

Lessons Learned From Recent DOJ/HHS Fraud Investigations, Prosecutions and Settlements

Strafford Publications, Inc. Teleconference

April 8, 2010

Michael W. Paddock, Esq.

Crowell & Moring LLP

1001 Pennsylvania Avenue NW

Washington DC 20004

(202) 624-2519

mpaddock@crowell.com

Impact of Fraud Enforcement and Recovery Act of 2009 ("FERA") on Potential Liability

- FERA significantly amended the False Claims Act, 31 U.S.C. §3729 *et seq.*
- Expanded definition of "claim"
  – Now includes claims made to contractors "if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest…"
- Expanded traditional, 31 U.S.C. §3729(a)(1) liability
  – "Presentment" no longer required
- Together: resolves any doubt that claims to Medicaid contractors and FHCP managed care organizations are subject to FCA

Impact of Fraud Enforcement and Recovery Act of 2009 on Potential Liability

- Expanded traditional, 31 U.S.C. §3729(a)(2) liability
  - Expanded liability to use of false records or statements "material" to a false or fraudulent claim… as opposed to use of false records or statements "to get" a false or fraudulent claim "paid or approved."
    - Reverses *Allison Engine Co. v. U.S. ex rel. Sanders*, 128 S.Ct. 2123 (June 7, 2008) (FCA defendant must *intend* for the government to pay claim).
    - "Material" now means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. §3729(b)(4).
- New definition of "material" may also reverse wealth of case decisions imputing "materiality" requirement to all FCA counts
  - Some prior courts: government or relator must prove that the false record or statement was material, that the government relied on it, and that such reliance directly and proximately caused government to make a (payment) decision that it would not have made had it known of the falsity.

crowell moring

Impact of Fraud Enforcement and Recovery Act of 2009 on Potential Liability

- Significant expansion of "reverse false claims" provision
- Old reverse false claim provision, 31 U.S.C. §3729(a)(7)
  - "Any person who… knowingly makes, uses, or caused to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government…."
- New reverse false claim provision, 31 U.S.C. §3729(a)(1)(G)
  - "Any person who… knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government…" (emphases added).

31 U.S.C. §3729(a)(1)(G)'s Third Actionable Offense

- "… knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government."
  - Expansion: actionable *without* use of record or statement
  - Expansion: actionable *without* falsity
  - Expansion: actionable *without actus reus*

31 U.S.C. §3729(a)(1)(G)'s Third Actionable Offense, cont.

- 31 U.S.C. §3729(a)(1)(G) includes key defined and undefined terms
- "Obligation" 31 U.S.C. §3729(b)(3)
  - "an <u>established duty</u>, whether or not fixed, <u>arising from</u> an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any <u>overpayment</u>…" (emphases added).
- "Established duty… arising from"
- "Overpayment"

crowell moring

What *Was* An “Obligation” Under Old (a)(7)?

- “Obligation” was an operative term under (a)(7), but defined *only* by the courts, *e.g.*:
  - *U.S. ex rel. Prawer v. Verrill & Dana*, 946 F.Supp. 87 (D. Me. 1996) (‘obligation’ does not include potential liabilities, only current liabilities)
  - *U.S. v. Q Int’l Courier, Inc.,* 121 F.3d 770 (8th Cir. 1997) (‘obligation’ does not include penalties due to undeclared violations of laws/regulations, or instances where administrative or prosecutorial discretion could interfere, or where selection of various applicable penalties and sanctions has not been made)
  - *American Textile Mfrs. Inst. v. The Limited, Inc.*, 190 F.3d 729 (6th Cir. 1999) (‘obligation’ does include acknowledgement of indebtedness, court judgment, administrative judgment, contractual duty… but not “contingent” obligations, *i.e.*, those “that will arise only after the exercise of discretion by government actors”)

What *Is* An “Obligation” / “Established Duty” Under New (a)(1)(G)?

- Consistent with previous, (a)(7) jurisprudence?
- “Obligation” now defined by statute as an “established duty… arising from” any one of eight prescribed sources:
  - Express contractual relationship
  - Implied contractual relationship
  - Grantor-grantee relationship
  - Licensor-licensee relationship
  - Fee-based or similar relationship
  - Statute
  - Regulation
  - Retention of overpayment

Obligations and Established Duties…?

- Contractual relationships:
  - Enrollment agreement (CMS Form 855)?
  - CCAs and CIAs
- Statutes:
  - 42 U.S.C. §1320a-7b(a)(3)?
  - 42 U.S.C. §1395nn(g)(2)? (requires refunds, but only to individuals)
  - 18 U.S.C. §§669, 1347?
- Regulations:
  - 42 C.F.R. §411.353(d) (requires refunds of "all collected amounts")
- When does (can?) an "established duty" to pay the Government "arise from" a mere retention of an overpayment?
  - Equitable theories of recovery?

crowell moring

New "Obligation" / "Established Duty"

- H.R. 3590: "Patient Protection and Affordable Care Act", §6402, "Enhanced Medicare and Medicaid Program Integrity Provisions" (March 23, 2010)
- "(d) REPORTING AND RETURNING OVERPAYMENTS.—
  - (1) IN GENERAL.-- If a person has received an overpayment, the person shall —
    - (A) report and **return the overpayment** to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address, and
    - (B) notify the Secretary, the State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.
  - (2) DEADLINE FOR REPORTING AND RETURNING OVERPAYMENTS.—An overpayment must be reported and returned under paragraph (1) by the later of---
    - (A) The date which is **60 days** after the date on which the overpayment was **identified**; or
    - (B) The date any corresponding cost report is due, if applicable.
  - (3) ENFORCEMENT.--Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is **an obligation** (as defined in section 3729(b)(3) of title 31 of the United States Code) for purposes of section 3729 of such title…" (emphases added).

What Is An “Overpayment”?

- §6402(d)(4)(B): “The term ‘overpayment’ means any funds that a person receives or retains under [Medicare] or [Medicaid] to which the person, after applicable reconciliation, is not entitled under such title.”
- Overpayments can be caused by, *e.g.*:
  - Lack of Medicare or Medicaid eligibility
  - Medicare improperly pays as the primary insurer
  - Services not statutorily covered
  - Services not medically necessary
  - Payment amount is incorrect and excessive

Other Impacts of Fraud Enforcement and Recovery Act of 2009

- Expanded conspiracy count, 31 U.S.C. §3729(a)(1)(C)
- Expanded and changed whistleblower protections
  - Expansion: no longer applies to just employees, but now also to contractors and agents
  - Change: whistleblowers protected from discrimination if…
    - Pre-FERA: "in furtherance of an action under [the FCA], including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under [the FCA]…"
    - Post-FERA: "in furtherance of efforts to stop 1 or more violations of this subchapter."

Other Impacts of Fraud Enforcement and Recovery Act of 2009

- Expanded government's investigative tools and capability
  - Civil Investigative Demands
    - Prior to FERA, only the Attorney General could authorize their use
    - FERA: authorized AG to delegate CID authority to designees
    - Recently, authority delegated to all U.S. Attorneys (75 Fed. Reg. 14070, Mar. 24, 2010)
    - Delegation could facilitate relators' pleading with specificity, dampen ability to use FRCP 9(b) as an FCA defense, assist criminal prosecutors without need to appear before grand jury
  - "Relation back"
    - FERA provision (adding 31 U.S.C. §3730(c)) may eviscerate minority rule that certain complaints-in-intervention do not relate back to relators' complaints

Retroactivity of Fraud Enforcement and Recovery Act of 2009?

- Amendment to 31 U.S.C. §3729(a)(1)(B) "shall take effect as if enacted on June 7, 2008, and apply to all claims under the [FCA] that are pending on or after that date" (emphasis added).
- Claims v. Cases
- Constitutionality of retroactivity

Current Trends in Fraud and Abuse Enforcement

Robert C. Threlkeld, Esq.
Morris, Manning & Martin, LLP
3343 Peachtree Road, N.E.
1600 Atlanta Financial Center
Atlanta, Georgia 30326-1044
404.504.7757
rthrelkeld@mmmlaw.com

MORRIS, MANNING & MARTIN, LLP

Expanded Government Enforcement Efforts

- In October 2009, Senator Grassley stated that the Federal Government then had approximately 1040 *qui tam* cases in which the Government had not yet decided to intervene.
- In addition, Senator Grassley stated that there were 130 pending *qui tam* cases in which the Government had joined. There were 490 cases in which the Government had declined to intervene.
- As to these cases, there were 985 health care fraud cases pending.
- There were 200 pending *qui tam* cases relating to pricing and marketing of pharmaceuticals.
- There were 205 *qui tam* cases alleging Department of Defense procurement fraud.

Important Provisions in Patient Protection and Affordable Care Act as Amended by Health Care and Education Affordability Reconciliation Act (the "Act")

- The Act increases by $250MM the funding for the Health Care Fraud and Abuse Control Fund over next ten years, to be adjusted by the CPI.
- Amends the Anti-Kickback Statute's ("AKS") intent standard and rejects heightened intent standard of Ninth Circuit in Hanlester that had required the Government to prove that a defendant (1) knew that the AKS prohibited the conduct; and (2) nevertheless engaged in the conduct with specific intent to disobey the law.
- The Amendment to the AKS does not eliminate the requirement, however, that the Government show that a defendant knew the conduct was unlawful.

Important Provisions in Patient Protection and Affordable Care Act as Amended by Health Care and Education Affordability Reconciliation Act (the "Act")

- The Act amends the False Claims Act to provide that a violation of the AKS constitutes a fraudulent act under the False Claims Act.
- The Act in tandem with the Fraud Enforcement and Recovery Act, expands liability for reverse false claims. The Act defines an "overpayment" as "any funds that a person receives or retains [from a federal payor] to which the person, after applicable reconciliation is not entitled . . . ." The Act provides that all overpayments must be refunded within 60 days after "identification" of the overpayment. The Act then clarifies that such a retention of an overpayment and repaying same is an "obligation" under the False Claims Act.

Important Provisions in Patient Protection and Affordable Care Act as Amended by Health Care and Education Affordability Reconciliation Act (the "Act")

- The Act also greatly expands the definition of an original source as a person who (1) has "voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based prior to a public disclosure, or (2) has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section."

Important Provisions in Patient Protection and Affordable Care Act as Amended by Health Care and Education Affordability Reconciliation Act (the "Act")

- The Act also lowers the intent requirement under the healthcare fraud criminal statute, 18 U.S.C. § 1347 – The Act eliminates the requirement that the Government show a specific intent to violate the statute.
- The Act will encourage self-disclosure of Stark Law violations in that the Secretary of HHS must develop a Stark self-disclosure protocol within six months that would permit the compromise of claims and penalties.

Principal Enforcement Areas in Hospital/Physician Relationships

- Focus on commercial reasonableness under Stark Law in physician/hospital alignment arrangements.
- Continued focus on fair market value in various physician/hospital relationships.
- Focus on medically unnecessary services in connection with in-patient admissions.
- Focus on outlier payments.
- Continued focus on more blatant instances on fraud for services not rendered.
- Increased focus on enforcement actions directed not only towards hospitals, but also physician participants in hospital /physician alignment initiatives.

Focus on Commercial Reasonableness

Tuomey Case – A Rare Stark Law Case that Proceeds to Trial and Verdict

- Jury rendered verdict in Tuomey case on March 29, 2010.
- Whistleblower suit brought by community physician alleging that 19 part-time employment contracts between Sumter Regional Medical Center with 19 surgeons of various sub-specialties violated Stark Law, 42 U.S.C. § 1395nn, and resulted in submission of numerous false claims.
- Contracts were executed after a CON had been obtained for a physician-owned ambulatory surgery center; Government contended that contracts were arranged solely to induce referrals of outpatient surgeries to Tuomey instead of the cases being performed at the ASC.

Focus on Commercial Reasonableness

Tuomey Case

- Government contended that part-time contracts were not at fair market value and were not commercially reasonable.
- Physician employment contracts only covered the provision of outpatient surgical procedures. All other services, including professional evaluation and management services, inpatient services and office-based procedures were specifically excluded. Under the contracts, the physicians were required to perform all outpatient procedures at Tuomey facilities.
- Contracts were for an initial 10-year term and contained a 30-mile non-compete for ASC procedures after their termination.
- Contracts each contained a base salary and a productivity bonus.

Focus on Commercial Reasonableness

Tuomey Case

- Base salaries for general surgeons, OBgyns and an ophthalmologist determined by net collections that Tuomey Specialty Group received for physician's covered services for prior year. Base would increase if physician's collections increased.
- Base salary for GI physicians based on number of covered outpatient procedures the prior year.
- Tuomey also paid 80% of cash collections as a productivity bonus and permitted a quality incentive of up to 5.4%.
- Contracts also provide health and dental insurance to GI physicians at no cost. Tuomey also paid a CME stipend of $5,000, paid other benefits, and paid the malpractice insurance for all non-OB physicians for all medical services the physician performed, regardless of whether they performed them at Tuomey.

Focus on Commercial Reasonableness

Tuomey Case

- Tuomey stated that because both base salary and bonuses were based on personal productivity measures, then they by definition could not vary with the volume or value of designated health services referrals.
- Tuomey consulted with independent counsel and consultants who had reservations about the structure of the arrangements.
- Tuomey contended that contracts were commercially reasonable and within FMV based on physician's personal productivity. Base salary for non-GI physicians based on personal productivity standards. Bonuses were paid solely based on personal productivity measures.

Focus on Commercial Reasonableness

Tuomey Case

- Evidence indicated that Tuomey understood it would lose money on the professional fees generated by the physicians as compared with the salaries for part time employment services but would profit from the technical service referrals.
- Government contended that the contracts could not meet the "employment exception" under Stark because the compensation was not within fair market value and was not commercially reasonable pursuant to 42 C.F.R. §§ 411.357(c)(2)(i) & (3).
- In pretrial motions practice the Government contended that "commercial reasonableness is an objective standard." (Memorandum in Support of Motion for Partial Summary Judgment at 38.)

Focus on Commercial Reasonableness

Tuomey Case

- A commercially-reasonable arrangement is one that would "make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty, even if there were no potential designated health service referrals." 69 Fed. Reg. at 16093.
- For these reasons, Government also contended that agreements could not meet the Stark indirect compensation exception set forth at 42 C.F.R. § 411.357(p).
- Jury found on March 29th that 10-year, part-time employment agreements violated Stark Law, but did not violate the False Claims Act.

Focus on Commercial Reasonableness

Memorial Health University Medical Center ("Memorial")

- In April 2008, Memorial in Savannah agreed to pay $5.08MM to settle a whistleblower lawsuit.
- In 1002, Memorial had negotiated new employment contracts with its employed ophthalmology group. The contract did not account for the physicians' teaching and indigent care services. To correct this, Memorial paid $500K to the physician group per year from 2003-2005, and $600K in 2006.

Focus on Commercial Reasonableness

Memorial Health University Medical Center (“Memorial”)

- The physician group did not distribute those funds pro rata, but only to certain physicians.
- Although the Government did not fully embrace the whistleblower physician’s theories, the Government did contend that the salaries of certain physicians were not “commercially reasonable” and not within fair market value.

Focus on Commercial Reasonableness

Covenant Medical Center – Waterloo, Iowa

- In August 2009, Covenant Medical Center agreed to pay the government $4-5MM to settle allegations that payments made to five employed physicians were not "commercially reasonable".
- Covenant's five highest paid physicians were paid between $2.1MM and $633,000 per year in 2002.
- Two orthopedic physicians were paid $2.14MM and $1.0MM, respectively, in 2002. A gastrointestinal specialist was paid $2.1MM that year.

Focus on Commercial Reasonableness

Covenant Medical Center – Waterloo, Iowa

- Covenant contended that the payments were well within fair market value based on personal productivity metrics.
- The Government contended that the payments were not ”commercially reasonable” based on what other physicians were making in the market.
- The concept of “commercial reasonableness” is extremely elastic and ill-defined under the Stark Law.

Cases and Trends Involving Fair Market Value and Various Equipment, Space and Service Agreements

Christ Hospital Settlement

- In February 2010, Christ Hospital in Cincinnati announced that it would settle with the Government in a whistleblower suit alleging that Christ Hospital had provided improper inducements to Ohio Heart Health Center cardiologists.
- Published articles in late-March 2010 estimated the total settlement at approximately $100MM.
- The whistleblower alleged that between 1999 and 2004 cardiologists were allocated preferential scheduling time at the "Heart Center" at Christ Hospital based on the number of CABG procedures and cardiac catheterization procedures that were performed the prior year.

Cases and Trends Involving Fair Market Value and Various Equipment, Space and Service Agreements

Christ Hospital Settlement

- According to the Complaint, the value of the allegedly improper inducements resulted from the ongoing patient business that cardiologists would receive from new patients at the Heart Center.
- Christ Hospital contended that the procedures for "new patients" that might be referred to cardiologists were low-cost procedures like EKGs and that the mere assignment of favorable scheduling times could not induce referrals from the cardiologists to the hospital for more complex procedures.
- As a predicate to this settlement, the United States District Court for the Southern District of Ohio had denied Christ Hospital's Motion to Dismiss. (*See* United States, ex rel. Fry v. Health Alliance of Greater Cincinnati, 2008 WL 5282139 (Dec. 18, 2008). It also denied a subsequent motion to certify an interlocutory appeal.

Cases and Trends Involving Fair Market Value and Various Equipment, Space and Service Agreements

Christ Hospital Settlement

- In ruling on the Motion to Dismiss, the Court rejected Defendants' argument that the term remuneration in the Anti-Kickback Statute, 42 U.S.C. § 1320a – 7b(b) could not include staff privileges or privileges in scheduling. The Court accepted as true for purposes of the Motion to Dismiss the Government's assertion that the arrangement provided the cardiologists with a cross-referral stream of patients.

Cases and Trends Involving Fair Market Value and Various Equipment, Space and Service Agreements

Christ Hospital Settlement

- The Court also rejected Defendants' argument that because neither the OIG nor any reported case had discussed preferential scheduling time, then the hospital supposedly must have lacked the requisite *mens rea* to violate the Anti-Kickback Statute.
- Furthermore, because the Complaint alleged that Defendants had actively sought to conceal the arrangement, then the Plaintiff adequately alleged reverse false claims through willful failure to disclose same.
- In denying the request to certify an interlocutory appeal, the Court held that it was "unconvinced that there is substantial ground for difference of opinion as to its conclusion that time in the TCH heart station could constitute 'remuneration' under the Anti-Kickback Statute. The referral system Defendants allegedly used that clearly profited Defendants to the exclusion of doctors shut out from work and opportunities to gain new patients, does not merely present a question of 'routine staffing decisions' or 'the opportunity to work.'" United States ex rel. Fry v. The Health Alliance of Greater Cincinnati, 2009 U.S. Dist. LEXIS 14963 at * 13 (Feb. 26, 2009).

Cases and Trends Involving Fair Market Value and Various Equipment, Space and Service Agreements

United States v. Kosenske

- Ongoing case involving allegations that defendant hospital violated the Stark Law and Anti-Kickback Statute through a service arrangement between a hospital and pain management physicians. (*See* 554 F.3d 88) (3rd Cir. 2009) (reversing grant of summary judgment to Carlisle HMA).
- Case arose out of exclusive agreement for physician group to provide anesthesia coverage. Pursuant to a 1992 written agreement, the hospital would provide personnel, equipment and supplies for anesthesia and pain management.
- In 1998, physician group began to provide same services in an outpatient surgery center that Carlisle operated. The physician group in both instances billed for professional services while the hospital would bill for services.

Cases and Trends Involving Fair Market Value and Various Equipment, Space and Service Agreements

United States v. Kosenske

- The hospital and the physician group did not enter into a new or amended contract to cover this same center.
- Because of the free use of space, equipment and personnel for pain management procedures and the lack of a contract to cover same, the 3rd Circuit held that both the Stark Law land Anti-Kickback Statute were implicated.
- On March 31, 2010, the district court denied cross motions for summary judgment. 2010 U.S. Dist. LEXIS 31619.

Cases and Trends Involving Fair Market Value and Various Equipment, Space and Service Agreements

United States v. Kosenske

- In so doing, the court noted that there was disputed evidence over the *scienter* element under the False Claims Statute, 31 U.S.C. § 3729(b). In particular, the court found that in-house counsel and compliance officers had a good faith belief that the 1992 writing covered the new arrangement.
- In denying summary judgment under the Anti-Kickback Statute, the court held that although the 3rd Circuit applied the "one purpose of payment" standard to satisfy the intent element under the AKS, still where was conflicting evidence whether the heightened *mens rea* standard under the Anti-Kickback Statute was satisfied. 2010 U.S. Dist. LEXIS at * 34.

Cases and Trends Involving Fair Market Value and Various Equipment, Space and Service Agreements

South Texas Hospitals Settlement

- In October 2009, McAllen Hospitals, L.P. d/b/a South Texas Health System agreed to pay $27.5MM to settle allegations that it violated False Claims Act, Anti-Kickback Statute and Stark Law.
- Government alleged that there were a series of sham contracts between the hospital, including medical directorships and lease agreements, that the hospital entered into to induce referrals.

Cases and Trends Involving Fair Market Value and Various Equipment, Space and Service Agreements

South Texas Hospitals Settlement

- The whistleblower, a former head of managed care contracting at the hospital system alleged a series of improper relationships, including interest-free and forgiven loans, free advertising, equipment, furniture, housekeeping and office space.
- Ironically, although the conduct took place in McAllen, TX, the Government did not allege and did not show any over-utilization.

Cases and Trends Involving Fair Market Value of Various Equipment, Space and Service Arrangements

Condell Health Network Case

- In December 2008, Condell Health Network, the parent corporation of Condell Medical Center in Libertyville, IL, agreed to pay $36MM to the Government for various improper hospital/physician relationships.
- Condell voluntarily self-disclosed the improper relationships while it was in the process of being acquired by Advocate Health Care.
- Among the allegedly improper relationships were:

  (a) Leases below fair market value;

  (b) Loans to physicians that did not reflect credit terms.

Cases and Trends Involving Fair Market Value of Various Equipment, Space and Service Arrangements

Condell Health Network Case

- Payments to physicians for services without the existence of written agreements to satisfy the personal services exception under Stark (42 U.S.C. § 1395(e)(3)(A)) and the Anti-Kickback Statute.

Cases and Trends Involving Fair Market Value of Various Equipment, Space and Service Arrangements

Cox Medical Center/Ferrell-Duncan Clinic

- July 2008 settlement by Cox Medical Center in Springfield, MO for $60MM.
- October 2008 settlement by Ferrell-Duncan Clinic.
- Whistleblower suit joined by Government claimed that from July 1, 1996 to December 31, 2005 Cox entered into improper service agreements with Ferrell-Duncan.
- The Government alleged, *inter alia,* that Cox paid nephrologists based on the number of patients referred to a Cox Medical dialysis clinic.

Cases and Trends Involving Fair Market Value of Various Equipment, Space and Service Arrangements

Cox Medical Center/Ferrell-Duncan Clinic

- The Government also alleged that Cox paid physicians based on the volume of referrals for DME, clinical lab services, various imaging services.
- Importantly, the Government did not contend that the services were medically unnecessary.

Cases Involving Improper Inpatient Admissions

Yale-New Haven Hospital

- In September 2006, Yale-New Haven voluntarily notified the OIG at HHS and the CMS intermediary that patients had improperly been admitted as inpatients following the provision of outpatient Gamma Knife stereotactic radiation procedures. Yale voluntarily sent a refund in the amount of $2,356,702 to CMS.
- After further investigation, Government determined that Yale-New Haven had also made improper inpatient admissions for Gamma Knife patients undergoing radiation treatments.
- In July 2009, Yale-New Haven agreed to pay an additional $885,953 to settle these allegations.

Cases Involving Improper Inpatient Admissions

St. Joseph's Atlanta Hospital Settlement

- In December 2007, St. Joseph's Hospital of Atlanta agreed to pay $26MM to resolve a whistleblower's allegations that certain short-stay inpatient admissions should have been billed instead as outpatient visits.
- Settlement also covered claims where the hospital admitted patients for three days so that patients would qualify under Medicare payment rules for subsequent skilled nursing facility services.
- Included as part of the settlement was the requirement that St. Joseph's adopt a case management protocol.

Kyphoplasty Settlements

- In September 2009, Government announced settlements of cases involving inpatient admissions for patients who underwent kyphoplasty.
- 3 Alabama hospitals and 3 Indiana hospitals agreed to pay $8.36MM in the aggregate.
- Government contended that these spine fracture repair patients, whose procedures were performed on an outpatient basis, did not warrant inpatient admissions.
- Certain hospitals who settled asserted that the inpatient admissions in fact were necessary, but that there was faulty medical record keeping only.

Cases Involving Clinical Research Conduct

Health Care Fraud and Abuse In A Tougher Enforcement Environment

Strategies for Implementing and Maintaining Compliance Programs

April 8, 2010

Michael A. Dowell
Partner
Hinshaw & Culbertson, LLP
mdowell@hinshawlaw.com

What is A Compliance Program?

- A system to ensure continuous compliance with all applicable laws, regulations, industry and organizational standards, principles of good governance and accepted community and ethical standards

- Required by law or contract for most health care organizations

Seven Elements of A Compliance Program

- Standards and Procedures
- Education and Training
- Oversight
- Monitoring and Auditing
- Reporting
- Enforcement and Discipline
- Response and Prevention

Why Are Compliance Programs Important?

- Raise Awareness
- Communicates Commitment
- Mitigation Factor

What is an "Effective" Compliance Program?

- To have an effective compliance and ethics program, an organization shall:
  - ✓ Exercise due diligence to prevent and detect criminal conduct; and
  - ✓ **Promote an organizational culture** that encourages ethical conduct and commitment to compliance.
- The compliance program should be **reasonable designed, implemented and enforced so that the program is generally effective in preventing and detecting criminal conduct**

What is an "Effective" Compliance Program?

- Establish **standards and procedures**
- **Governing authority** should be knowledgeable about compliance and **exercise reasonable oversight**
- Take reasonable steps to **communicate periodically** and **in a practical manner** its standards and procedures, including **effective training** programs
- **Consistent** promotion and enforcement of compliance program
- **Respond appropriately** to criminal conduct and **prevent further** criminal conduct

How Can You Tell if Your Compliance Program is Effective?

- Is the compliance program well designed?
- Is the compliance program being applied earnestly and in good faith?
- Does the compliance program work?

Why Are Effective Compliance Programs Important?

- We need to establish a defense to negate knowledge under the False Claims Act and other criminal laws.

- *United States v. Merck Managed Care*, 336 F. Supp. 2d 430 (E.D. Pa. 2004)
  - ✓ Compliance weaknesses equal "reckless disregard"; and
  - ✓ Lack of an effective compliance program enough to establish submission of false claims "knowingly."

Compliance Plans Are Not Working

- DOJ and OIG have fined and penalized numerous health care organizations who have mad substantial investments in compliance programs
- In each case, the DOJ/OIG determined that the compliance plans were “ineffective”

Why Are Most Compliance Programs Ineffective?

- Compliance Is Not A High Priority
- The Written Compliance Program Has Not Been Implemented Or Operated
- Compliance Department Financial Resources Are Inadequate
- Risks Assessments Do Not Address Issues Noted In Available Resources

Why Are Most Compliance Programs Ineffective?

- Compliance Violation Reporting Mechanisms Not Advertised
- Compliance Education and Training Is Ineffective
- Compliance Complaints Are Not Appropriately Investigated Or Resolved
- Disciplinary Standards Are Not Consistently Enforced

What Does One Need To Do To Have An "Effective" Compliance Program?

- Participation of Leadership
- Effective Communication of Standards and Procedures
- Effective Audits that Uncover Issues
- Targeted Monitoring and Reporting Systems
- Consistent Enforcement of Standards
- Appropriate Responses to Offenses

Implementation of an Effective Compliance Program

- Board and Organizational Support of the Compliance Program
- Consistent Compliance with Code of Conduct and Policies & Procedures
- Effective Education and Training
- Monitoring and Auditing
- Effective Lines of Communication

Implementation of an Effective Compliance Program

- Responding to Detected Offenses & Corrective Action
- Compliance As An Element of Employee Performance & Enforcement of Disciplinary Guidelines
- Risk Assessments

Why Is Voluntary Disclosure Important to Consider?

- Prompt Disclosure Can Reduce the Chances That the Case or Matter Will Turn into a Criminal Investigation.

- Timely Disclosure Can Reduce Potential Damages Under the False Claims Act.

- Timely Disclosure Can Eliminate the Risk of a Qui Tam Action.